CASE HX0117A-CIP DIV 1

REMARKS

Claims 17 to 36 and 42 are present for purposes of prosecution.

Claims 12, 14, 15, 41, 43 and 44 have been withdrawn as being directed to a non-elected invention. Claims 12, 14, 15, 41, 43 and 44 have been cancelled to expedite prosecution of this application. However, Applicants reserve the right to file a divisional application to cover these claims.

Reconsideration of the rejection of this application is respectfully requested in view of the above amendments and the following remarks.

Applicants affirm their election of Group II Claims 17-36 and 42.

The Specification has been amended to indicate that the present application is a division of U.S. Application Serial No. 10/008,154 as suggested by the Examiner.

Claims 17-36 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states as follows:

"a. Claim 17,

- What are the 'other therapeutic agents' or 'other cardiovascular agents'?
 A definition is not found in the specification. The term 'including' is unclear since the therapeutic agents or cardiovascular agents other than those recited as being included have not been described.
- Are the 'platelet aggregation inhibitors' different from the 'anti-platelet agents' under the 'cardiovascular agents'?
- The term 'modulating' in 'lipid modulating agents' is unclear as to the
 positive or negative changes intended by the applicant. If only lipidlowering agents are intended, it would be a duplicate of the earlier recited
 lipid-lowering agents.
- What are 'lipid agents'?

b. Claim 42,

- What are the 'related diseases'? A definition is not found in the specification. The rejection is applicable to claims dependent on the above claims.
- The term 'modulating' in 'lipid modulating agents' is unclear as to the positive or negative changes intended by the applicant,
- What is the 'other type of therapeutic agent'?"

CASE HX0117A-CIP DIV 1

a. Claim 17 has been amended to delete the terms "other therapeutic agents", "other cardiovascular agents", and "including."

The term "anti-platelet agents" includes "platelet aggregation inhibitors" and thus the latter term has been deleted.

The term "lipid modulating agents" is defined at page 12, lines 4 to 8 of the specification. The term "lipid agents" is defined on page 39, lines 29 to 34, and page 40, lines 4 to 37.

b. With regard to Claim 42, the term "related diseases" has been deleted. The term "lipid modulating agent" has been dealt with above.

The term "other type of therapeutic" has been deleted from Claim 42.

In view of the above, it is submitted that the rejection of Claims 17 to 36 and 42 under 35 U.S.C. 112, second paragraph has been overcome.

Claims 17 to 36 and 42 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement.

The Examiner objects to some of the combinations of the invention which include, among others, anti-cancer agents and anti-Alzheimer agents. Applicants have fully disclosed utilities and examples of each of the other therapeutic agents which are to be employed in combination with the HMG CoA reductase inhibitors. There is no reason to assume that the combinations claimed cannot be employed together. There is nothing in the references mentioned by the Examiner that would suggest that the claimed combinations should not be employed. The burden is on the Patent Office to prove that otherwise known drugs cannot be used in combination with the HMG CoA reductase inhibitors claimed herein.

CASE HX0117A-CIP DIV 1

In view of the foregoing, it is submitted that Applicants' Specification teaches one skilled in the art as to how to use the invention claimed herein including dosages and utilities. Accordingly, it is believed that the objection under 35 U.S.C. 112 first paragraph has been overcome.

It is now believed that Claims 17 to 36 and 42 are in condition for allowance.

Respectfully submitted,

Bristol-Myers Squibb Company Patent Department P.O. Box 4000 Princeton, NJ 08543-4000 (609) 252-4336

Date: April 15,2004

Burton Rodney

Attorney for Applicants

Reg. No. 22,076